

## CLAIMS

What is claimed is:

1. An lumen opening device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel.

2. The intravascular device of Claim 1 wherein said at least one helical pump also serves as a helical drive cable.

3. The intravascular device of Claim 2 wherein said helical drive cable comprises a two start helical spring.

4. The intravascular device of Claim 2 wherein said helical drive cable is arranged with variable pitch.

5. The intravascular device of Claim 1 wherein said inner catheter comprises an introducer sheath or guide catheter.

6. The intravascular device of Claim 1 wherein said infusate comprises therapy means.
7. The intravascular device of Claim 6 wherein said therapy means comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.
8. The intravascular device of Claim 7 wherein said biologically active material comprises a growth factor.
9. The intravascular device of Claim 7 wherein said drug comprises heparin or urokinase.
10. The intravascular device of Claim 1 additionally comprising a debris blocking member.
11. The intravascular device of Claim 10 wherein said debris blocking member comprises a balloon.
12. The intravascular device of Claim 1 wherein said infusate liquid is introduced adjacent said working head.
13. The intravascular device of Claim 1 wherein said infusate liquid exits said working head.
14. The intravascular device of Claim 13 wherein said working head is rotatable.
15. The intravascular device of Claim 13 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.
16. The intravascular device of Claim 13 wherein said helical pump also serves as a helical drive cable.
17. The intravascular device of Claim 15 wherein said working head does not engage occlusive material.
18. The intravascular device of Claim 1 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.
19. The intravascular device of Claim 1 wherein said working head comprises an occlusion opening device.
20. The intravascular device of Claim 2 wherein said working head comprises an occlusion opening device.

21. The intravascular device of Claim 19 wherein said occlusion opening device comprises a balloon angioplasty catheter, an ultrasonic catheter, a laser catheter, a stent-delivery catheter, a rotary abrasive head, or a rotary cutting head.

22. The intravascular device of Claim 20 wherein said occlusion opening device comprises a balloon angioplasty catheter, an ultrasonic catheter, a laser catheter, a stent-delivery catheter, a rotary abrasive head, or a rotary cutting head.

23. The intravascular device of Claim 22 wherein said rotary cutting head comprises an impeller.

24. The intravascular device of Claim 20 wherein said working head comprises a balloon angioplasty catheter, an ultrasonic catheter, a laser catheter, a stent-delivery catheter, a rotary abrasive head, or a rotary cutting head.

25. The intravascular device of Claim 23 wherein said impeller is arranged to be rotated by said helical drive cable.

26. The intravascular device of Claim 25 wherein said instrument further comprises a proximal end, a distal end, and a shroud, wherein said shroud is attached to said distal end.

27. The intravascular device of Claim 26 wherein said shroud is arranged to at least partially cover said working head, and said shroud comprises an opening.

28. The intravascular device of Claim 27 wherein said impeller projects out of said opening.

29. The intravascular device of Claim 27 wherein any debris produced is progressively reduced in size until it is aspirated.

30. The intravascular device of Claim 29 wherein said infusate expedites the treatment.

31. An intravascular system for treating a lumen in a portion of blood vessel of a living being's vascular system, said blood vessel being occluded by an occlusive material, said intravascular system comprising a lumen-opening member for introduction into the lumen of the blood vessel, debris blocking means, and pump means, said lumen-opening member being arranged to act on the occlusive material in the interior of the occluded blood vessel to open the lumen for the freer flow of blood therethrough, said lumen opening

member comprising a working head, whereupon some debris may be produced from the occlusive material by the action of said lumen-opening member, said debris blocking means being arranged to be located within the occluded blood vessel distally of said lumen opening member for preventing debris from flowing distally of said debris blocking means, said pump means introducing an infusate liquid at a first flow rate and withdrawing said liquid at a second and higher flow rate to create a differential flow adjacent said lumen-opening member, said infusate liquid comprising therapy means, whereupon any debris produced by the action of said lumen-opening member is withdrawn with said liquid by said differential flow for collection remote from the occluded vessel portion and is prevented from flowing into any upstream blood vessel or downstream blood vessel.

32. The intravascular system of Claim 31 wherein said intravascular system comprises a catheter, and wherein said infusate liquid and the debris therein are withdrawn from the occluded blood vessel portion through said catheter.

33. The intravascular system of Claim 31 wherein said therapy comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.

34. The intravascular system of Claim 33 wherein said biologically active material comprises a growth factor.

35. The intravascular system of Claim 33 wherein said drug comprises heparin or urokinase.

36. The intravascular system of Claim 31 wherein said infusate liquid is introduced adjacent said working head.

37. The intravascular system of Claim 31 wherein said infusate liquid exits said working head.

38. The intravascular system of Claim 32 wherein said infusate liquid exits said working head.

39. The intravascular system of Claim 38 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.

40. The intravascular system of Claim 39 wherein said working head does not engage occlusive material.

41. The intravascular system of Claim 40, wherein said working head further comprises a thrombectomy device.

42. The intravascular system of Claim 41, wherein said therapy comprises urokinase.

43. The intravascular system of Claim 31 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.

44. The intravascular system of Claim 31 wherein said working head comprises any occlusion opening device.

45. The intravascular system of Claim 44 wherein said device comprises a balloon angioplasty catheter, an ultrasonic catheter, a laser catheter, a stent-delivery catheter, a thrombectomy device, a rotary abrasive head, or a rotary cutting head.

46. The intravascular system of Claim 31 wherein said working head comprises an ultrasonic catheter.

47. The intravascular system of Claim 32 wherein said intravascular system additionally comprises a second catheter.

48. The intravascular system of Claim 47 wherein said second catheter is arranged to deliver said infusate or irrigation liquid.

49. An intravascular system for treating a lumen in a blood vessel of a living being, the blood vessel being occluded by an occlusive material therein, said intravascular system comprising a working head, a pump means, and barrier means, said working head being arranged to operate on the occlusive material in the interior of the occluded blood vessel to open a lumen therein for the freer flow of fluid therethrough, whereupon some debris may be produced from the occlusive material by the operation of said working head, said barrier means being arranged for location downstream of said working head and activatable to restrict the flow of the debris downstream of said barrier means, said pump means introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second flow rate higher than said first flow rate, thereby creating a differential flow, said infusate liquid comprising therapy means, whereupon any debris produced by the

operation of said working head is withdrawn with said liquid by said pump means for collection remote from the occluded vessel portion.

50. The intravascular system of Claim 49 wherein said barrier means comprises an expandable member.

51. The intravascular system of Claim 50 wherein said expandable member comprises a balloon.

52. The intravascular system of Claim 49 wherein said therapy comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.

53. The intravascular system of Claim 52 wherein said biologically active material comprises a growth factor.

54. The intravascular system of Claim 52 wherein said drug comprises heparin or urokinase.

55. The intravascular system of Claim 49 wherein said system additionally comprises a flexible instrument and wherein said working head comprises a portion of said instrument, said instrument being arranged to be passed through the being's body so that said working head is located adjacent the occluded vessel portion.

56. The intravascular system of Claim 55 wherein said barrier means forms a portion of a guide wire, said guide wire extending through said instrument.

57. The intravascular system of Claim 56 wherein said guide wire is arranged to provide a perfusion liquid downstream of said barrier means.

58. The intravascular system of Claim 56 wherein said barrier means comprises an expandable member.

59. The intravascular system of Claim 57 wherein said perfusion liquid comprises said infusate, blood, or oxygenated liquid.

60. The intravascular system of Claim 59 wherein said infusate is oxygenated.

61. The intravascular system of Claim 57 wherein said perfusion liquid comprises said infusate liquid and said therapy comprises a drug, pharmaceutical, or a biologically active material.

62. The intravascular system of Claim 61 wherein said biologically active material comprises a growth factor.

63. The intravascular system of Claim 61 wherein said drug comprises heparin or urokinase.

64. The intravascular system of Claim 58 wherein said expandable member comprises a balloon.

65. The intravascular system of Claim 49 wherein said infusate liquid is introduced adjacent said working head.

66. The intravascular system of Claim 49 wherein said infusate liquid exits said working head.

67. The intravascular system of Claim 66 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.

68. The intravascular system of Claim 67 wherein said working head does not engage occlusive material.

69. The intravascular system of Claim 68 wherein said working head further comprises a thrombectomy device.

70. The intravascular system of Claim 49 wherein said therapy comprises urokinase.

71. The intravascular system of Claim 49 wherein said working head comprises a balloon angioplasty catheter, an ultrasonic catheter, a laser catheter, a stent-delivery catheter, a thrombectomy device, a rotary abrasive head, or a rotary cutting head.

72. The intravascular system of Claim 55 wherein said working head comprises an ultrasonic catheter.

73. A method for treating a lumen in a portion of a blood vessel of a living being's vascular system, the blood vessel portion being occluded by an occlusive material, the occluded blood vessel portion being located distally of a patent blood vessel portion, said method comprising:

(a) extending a first catheter through said patent blood vessel portion into said occluded blood vessel portion, said first catheter having a distal end portion and a port located proximally of said distal end portion;

(b) extending a second catheter through said first catheter so that a working portion of said second catheter is located in the occluded blood vessel portion;

(c) blocking the occluded blood vessel portion distally of said working portion of said second catheter;

(d) using said second catheter to open a lumen in the occluded portion of the blood vessel for the freer flow of blood therethrough;

(e) introducing an infusate into said occluded blood vessel portion and withdrawing said infusate and any debris produced by the opening of the occluded portion of the blood vessel through a passageway in said first catheter, wherein said infusate comprises therapy means; and

(f) providing a path for blood from the patent blood vessel portion to flow through said port into said passageway for merger with said infusate and debris.

74. The method of Claim 73 wherein said therapy comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.

75. The method of Claim 74 wherein said biologically active material comprises a growth factor.

76. The method of Claim 74 wherein said drug comprises heparin or urokinase.

77. The method of Claim 73 additionally comprising the step of:

(g) introducing a third catheter through said first catheter, said third catheter being arranged to carry a stent into the lumen formed in the occluded blood vessel to hold said lumen open.

78. The method of Claim 73 additionally comprising the steps of:

(g) extending a third catheter through said first catheter, said third catheter being arranged for introducing said infusate into said occluded blood vessel portion.



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79. A method for treating a lumen in a portion of a blood vessel of a living being's vascular system, the blood vessel being occluded by an occlusive material, the blood vessel being located distally of a patent blood vessel, said method comprising:

(a) extending a first catheter through said patent blood vessel portion into said occluded blood vessel portion, said first catheter having a distal end portion and a port located proximally of said distal end portion;

(c) blocking the flow of blood and debris distally of said working head;

(b) providing a vessel-opening catheter having a working head, and extending said vessel-opening catheter through said first catheter so that said working head is located in the occluded blood vessel portion, said first catheter and said vessel-opening catheter defining a passageway therebetween;

(d) operating said working head to open the occluded blood vessel portion for the freer flow of blood therethrough;

(e) introducing an infusate comprising a therapy means at a first flow rate adjacent said working head and withdrawing said infusate at a second and higher flow rate to create a differential flow adjacent said working head, whereupon blocked debris is withdrawn with said infusate for passage proximally through said passageway; and

(f) providing a path for blood within said patent blood vessel portion to flow into said passageway for merger with said infusate and debris.

80. The method of Claim 79 wherein said therapy comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.

81. The method of Claim 80 wherein said biologically active material comprises a growth factor.

82. The method of Claim 80 wherein said drug comprises heparin or urokinase.

83. A method for treating a lumen in a portion of a blood vessel of a living being's vascular system, the blood vessel being occluded by an occlusive material, the occluded blood vessel being located distally of a patent blood vessel portion, said method comprising:

(a) extending a guide catheter through said patent blood vessel portion into said occluded blood vessel portion;

(b) extending a lumen-opening catheter having a working head through said guide catheter so that said working head is located in the occluded blood vessel portion, said guide catheter and said lumen-opening catheter defining a fluid-flow

passageway therebetween;

(c) blocking the flow distal of said working head of blood and any debris created;

(d) operating said working head to open the lumen for the freer flow of blood therethrough, wherein said operation comprises introducing an infusate at a first flow rate at said working head and withdrawing said infusate at a second and higher flow rate to create a differential flow at said working head, whereupon debris is withdrawn with said infusate for passage proximally through said fluid-flow passageway, wherein said infusate comprises therapy means; and

(e) providing a path for blood within the patent blood vessel portion to flow into said fluid-flow passageway for merger with said infusate and the debris.

84. The method of Claim 83 wherein said therapy comprises a drug, pharmaceutical, a biologically active material, or microspheres carrying chemicals.

85. The method of Claim 84 wherein said biologically active material comprises a growth factor.

86. The method of Claim 84 wherein said drug comprises heparin or urokinase.

87. The method of Claim 83 wherein said working head is arranged to introduce said infusate liquid in the form of liquid jets.